SHANGHAI MOTEX HEATHCARE CO., LTD.
No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China
Telephone: 86-21-5979 9888 Fax: 86-21-23010718

II. 510(K) Summary of Safety and Effectiveness

(Per 21 CFR 807.92)

JUN 0 4 2014

K123126

2.1. General Information Establishment

- Manufacturer: **Shanghai Motex Healthcare Co., Ltd.**
- Address: No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China
- Owner Number: **9041164**
  Registration Number: **9615978**
- Contact Person: Dr. Jen, Ke-Min
  E-mail: ceirs.jen@msa.hinet.net Tel: +886-3-5208829 ; Fax: +886-3-5209783
- Date Prepared: May 23, 2014

Proprietary Name:

Subject Device:

- MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6412 Nature
  MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6412 Blue
  MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6512 Nature
  MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6512 Blue
- **Common Name:** Surgeon's glove
- **Classification Name:** Surgeon's Gloves
- **Product Code:** KGO, Class I
- Regulation Number: 878.4460

Predicate device:

- Esteem SMT Polyisoprene Powder-Free Surgical Sterile Gloves **(K093300)**

2.2. Safety and Effectiveness Information

- **Predicate Device:**
  Claim of Substantial Equivalence (SE) is made to Esteem SMT Polyisoprene Powder-Free Surgical Sterile Gloves **(K093300)**
- **Device Description:**

  Motex Powder-free Polyisoprene Surgical Sterile Gloves, Model # 6412_Nature, 6412_Blue; 6512_ Nature, 6512_Blue are made of synthetic rubber. The sterile gloves are sterilized by the radiation method. 6412_Nature, 6412_Blue are of thin gloves. 6512_Nature, 6512_Blue are of thick gloves. They are processed by special treatment with no protein, and intended to be used in surgery to prevent the cross contamination between patients and users.

SHANGHAI MOTEX HEALTHCARE CO., LTD.
No.369, Jiasong Zhong Road, Huaxin, Qingpu, Shanghai, 201708, China
Telephone: +86-21-5979 9888 Fax: +86-21-23010718

Motex Polyisoprene Powder-free Surgical Gloves variant models

Model	Size	Product Description						
		Hand shape	Surface	Beaded cuff	Sterile	Color	Size	
							Length (min)	Thickness (min)
6412	6, 6.5, 7, 7.5, 8, 8.5 (Sterile)	Curved Finger	Textured	•	•	Nature Blue	280±6 mm	0.13±0.03 mm
6512	6, 6.5, 7, 7.5, 8, 8.5 (Sterile)	Curved Finger	Textured	•	•	Nature Blue	280±6 mm	0.15±0.03 mm

- **Indications for Use:**

  MOTEX Polyisoprene Powder-Free Sterile Surgical Gloves are powder-free surgeon's glove made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

- **Device Characteristics:**

  a. Single use only.

  b. Not made with natural rubber latex.

- **Powder Residual:**

  Surgeon's gloves meet powder level requirements for Powder-free" designation per ASTM D6124-06 (Reaffirmation 2011), Standard test method for residual powder on medical gloves.

  The results generated values will be below 2mg of residual powder per glove.

- **Biocompatibility Test Reports:**

  There are complied with the biological evaluation and the results of these studies show that the MOTEX Polyisoprene Powder-free Sterile Surgical Glove safety for its intended use, including:

  - Systemic Intravenous Injection
  - Systemic Intraperitoneal Injection
  - Skin Sensitization Test (Maximization test), Sesame oil extract;
  - Sensitization Test (Maximization test), Sodium Chloride extract;
  - Skin Irritation Test, Sesame oil extract;
  - Skin Irritation Test, Sodium Chloride extract;

- **Clinical Data:**

  Not applicable.

- **Comparison between the subject devices and the predicate device**

Comparison Table

Feature	Predicate device	Subject device
Proprietary name	Esteem SMT Polyisoprene Powder-Free Surgical Sterile Gloves	Motex Powder-free Polyisoprene Surgical Gloves
510(k) number	**K093300**	**K123126**
Model	SMT	6412 (nature, blue) 6512 (nature, blue)
Indications For Use	Powder-Free Polyisoprene Surgical Gloves are sterile disposable devices made of imported synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination in the environments within hospitals and other healthcare facilities.	MOTEX Polyisoprene Powder-Free Sterile Surgical Gloves are powder-free surgeon's glove made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.
Prescription/OTC Device	Over-the-Counter Use	Over-the-Counter Use
Product code	KGO	KGO
Classification	Class I	Class I
Regulation number	878.4460	878.4460
Manufacturing material	Synthetic Polyisoprene	Synthetic Polyisoprene
Specifications		
Size	N/A	Size: 6, 6.5, 7, 7.5, 8, 8.5
Length (mm)	N/A	280±6
Width (mm)	N/A	size 6--77, size 6.5- 84, size 7-- 91, size 7.5-- 98, size 8-- 102, size 8.5—108
Thickness (finger, palm, cuff) (mm)	N/A	(6412)— 0.13±0.03, 0.13±0.03 (6512)— 0.15±0.03, 0.15±0.03

Tensile strength (before and after aging),	N/A	Before aging: 24 Mpa After aging: 23 Mpa
ultimate elongation (%) (before and after aging)	N/A	Before aging : 929% After aging : 879%
Test for Pinhole, Dimensions, and Physical properties	Meets ASTM D3577-09	Meets ASTM D3577-09
Residual powder testing	Meets ASTM D 6124-06 Residual powder < 2mg	Meets ASTM D6124-06 (Reaffirmation 2011) Residual powder < 2mg
Water leak testing(AQL)	Meets ASTM D 5151-06 (AQL=1.5)	Meets ASTM D 5151-06 (Reapproved 2011) (AQL=1.5)
Water extractable protein testing	Meets ASTM D 5712-10 No protein content	Meets ASTM D 5712-10 No protein content
Biocompatibility	non irritant non sensitizing	non irritant non sensitizing
Sterilization Validation	Pass ISO11137-1 ISO11137-2 Sterilization Assurance Number: 1×10^{-6}	Pass ISO11137-1:2006 (Amendment 1:2013) ISO11137-2:2013 Sterilization Assurance Number: 1×10^{-6}

- **Discussion of the similarities**

The same performance data of the Motex Powder-free Polyisoprene Sterile Surgical Gloves compared to the predicate device are summarized below.

Characteristics	Standard
Dimensions	meets ASTM D 3577-09,
Physical Properties	meets ASTM D 3577-09,
Freedom from Holes	meets ASTM D 3577-09,
Residual powder testing	meets ASTM D 6124-06 (Reaffirmation 2011)
Water leak testing	meets ASTM D 5151-06 (Reapproved 2011)
Water extractable protein testing	meets ASTM D 5712-10
Biocompatibility	non irritant & non- sensitizing ISO10993-10:2010 ISO10993-12:2012
Sterilization Validation	Pass ISO11137-1:2006 (Amendment 1:2013) ISO11137-2:2013

The subject device and the predicate device have the similar indications for use, the same material composition with Polyisoprene, the same technological characteristics, and the same biocompatibility and sterilization validation testing. There are no safety or effectiveness aspects raising.

- **Discussion of the differences**

  The minor differences between them are thickness and size. Both of them meet ASTM D 3577-09, ASTM D 6124-06 (Reaffirmation 2011), ASTM D 5151-06 (Reapproved 2011), ASTM D 5712-10, and biocompatibility testing. The safety or effectiveness aspects are not raised.

- **Conclusion**

  The conclusions drawn from the non-clinical tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in the submission.

Dr. Jen, Ke-Min
510(k) correspondent person for
Shanghai Motex Healthcare Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

JUL 18 2014

Shanghai Motex Healthcare Co., Ltd
Dr. Jen, Ke-Min
No. 369 Jiasong Zhong Road,
Huaxin, Qingpu
Shanghai 201708
CHINA

Re: K123126
Trade/Device Names: MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6412 Nature;
MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6412 Blue;
MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6512 Nature;
MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6512 Blue

Regulation Number: 21 CFR 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: April 26, 2014
Received: May 5, 2014

Dear Dr. Jen, Ke-Min:

This letter corrects our substantially equivalent letter of June 4, 2014.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration **Indications for Use**	Form Approved: OMB No. 0910-0120 Expiration Date: January 31, 2017 See PRA Statement below

510(k) Number (if known)

K123126

Device Name

MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6412 Nature

MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6412 Blue

MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6512 Nature

MOTEX Polyisoprene Powder-free Sterile Surgical Gloves, Model 6512 Blue

Indications for Use (*Describe*)

MOTEX Polyisoprene Powder-Free Sterile Surgical Gloves are powder-free surgeon's glove made of synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination. The lubricating or dusting powder used in the glove is excluded.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (*Signature*)

Elizabeth F. Claverie -S

Digitally signed by Elizabeth F. Claverie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 2.16.840.1.19200300.100.1.1=1300055844, cn=Elizabeth F. Claverie -S
Date: 2014.06.04 15:41:23 -04'00'

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services

Food and Drug Administration

Office of Chief Information Officer

Paperwork Reduction Act (PRA) Staff

PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."